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The National Women's Health Information Center

A project of the U.S. Department of Health and Human Services, Office on Women's Health



## Frequently Asked Questions about Hormone Therapy

### What is hormone therapy?

Hormone therapy (HT) provides women with the female hormones that decrease as they age. When the hormone estrogen is given alone, it is usually referred to as "ERT." When the hormone progesterin is combined with estrogen, it is generally called "HT," formerly known as hormone replacement therapy (HRT). Estrogen is a female hormone that brings about changes in other organs in the body. Progesterone is a female hormone that prepares the uterus for a pregnancy each month. During the transition to menopause ("perimenopause") these hormone levels start to fluctuate, causing some uncomfortable symptoms. When the ovaries stop producing estrogen and progesterone, menstrual periods cease and the woman has experienced menopause.

### What are the benefits of hormone therapy?

Hormone therapy has been used to relieve the short-term symptoms of menopause, such as hot flashes, sweats, and disturbed sleep. Preliminary evidence shows that HT may be helpful in preventing colon cancer, and macular degeneration (age-related vision loss).

### What are the risks of hormone therapy?

**Short-term side effects:** Some women report side effects from taking Hormone Therapy, including unusual vaginal discharge and bleeding, headaches, nausea, fluid retention and swollen breasts. Some women think HT will make them gain weight while taking HT, but research now shows this is not true. Some women do gain weight during menopause, but it is because their metabolism slows down as they age, and they may not be increasing their amount or level of physical activity. Short-term benefits or side effects should become apparent within weeks or months after treatment begins.

### Long-term risks (These will not be readily apparent for each individual woman):

**Cancer:** There is concern that HT can increase the risk of some cancers. When estrogen is taken alone, it raises the risk of endometrial cancer (lining of the uterus). Adding progesterin with estrogen (HT) can dramatically reduce this risk. Progesterin is added to prevent the overgrowth (or hyperplasia) of cells in the lining of the uterus, so women who still have an intact uterus are generally given this combined therapy.

The National Institutes of Health's (NIH) Women's Health Initiative (WHI) stopped a major clinical trial early on July 9, 2002 due to finding an increased risk of invasive breast cancer from HT with estrogen and progesterin. The increased risk of breast cancer appeared after 4 years of hormone use. After 5.2 years, estrogen plus progesterin use resulted in a 26 percent increase in the risk of breast cancer-or 8 more breast cancers each year for every 10,000 women. Women who had used estrogen plus progesterin before entering the study were more likely to develop breast cancer than others, indicating that the therapy may have a cumulative effect.

For more information on this study, go to <http://www.nhlbi.nih.gov> and click on "Postmenopausal Hormone Therapy," or call the number listed at the end of this FAQ, in the "For more information" section. The WHI is also looking at the effect of taking estrogen alone (this is given to women who have had a hysterectomy, or no longer have a uterus, or womb) on heart disease and other conditions; results should be available in the next few years, or sooner.

Regarding ovarian cancer, an observational study, supported by the NIH's National Cancer Institute (NCI), recently found that estrogen-only therapy appeared to increase the risk of ovarian cancer. But other, similar studies have not found such an increased risk, and the possible relationship between estrogen use and ovarian cancer remains unclear.

The decision to take HT should be based on an overall look at the risk and benefits and how they fit with your personal health profile.

**Breast Density:** Taking both estrogen and progestin also can affect a woman's breast density. Increased breast density from HT makes it more difficult for a radiologist to read some mammograms, leading to the need for follow-up mammograms or breast biopsies. Increased density also is a concern because other studies have shown that women age 45 and older whose mammograms show at least 75 percent dense tissue are at increased risk for breast cancer. However, it is not known if increased breast density due to HT carries the same risk for breast cancer as having naturally dense breasts.

Data from the Postmenopausal Estrogen/Progestin Interventions (PEPI) trial at NCI indicate that about 25 percent of women who use combined HT have an increase in breast density on their mammograms, compared to about 8 percent of women taking estrogen alone. One study showed that stopping HT for about 2 weeks before having a mammogram improved the readability of the mammogram. However, further research is needed to confirm the usefulness of this approach.

**Heart Disease:** In the past, taking HT (estrogen plus progestin) was thought to help protect women against heart disease. But recent findings from the Women's Health Initiative (WHI) study showed that taking HT poses more risks than benefits. The study found that HT could increase a woman's risk for heart disease, stroke, and pulmonary embolism (blood clot in the lung), as well as breast cancer. Because of these findings, the U.S. Preventive Services Task Force recommends that women who have gone through menopause should not be given HT to prevent heart disease and other chronic conditions. For more information on this study, go to <http://www.nhlbi.nih.gov> and click on "Postmenopausal Hormone Therapy," or call the number listed at the end of this FAQ, in the "For more information" section. The WHI is also looking at the effect of taking estrogen alone (this is given to women who have had a hysterectomy, or no longer have a uterus, or womb) on heart disease and other conditions; results should be available in the next few years, or sooner.

Earlier studies have also shown that women who have gone through menopause and who have heart disease, may have a greater risk of another cardiac event (like heart attack) after starting HT, at least in the short-term. For women who have had strokes, their risk for having another stroke goes up when they start taking HT. Hormones are not recommended for women with heart disease or for women who have had a stroke. If you have gone through menopause, talk with your health care provider about whether hormones are right for you. And, keep checking the NWHIC website home page ([www.4woman.gov](http://www.4woman.gov)) for updates on postmenopausal hormone therapy.

If you are taking HT, watch for signs of trouble, such as abnormal bleeding, breast lumps, shortness of breath, dizziness, severe headaches, pain in your calves or chest, and report them to your health care provider right away. Also, talk with your health care provider about how often you should have an exam.

## **Does the duration of taking HT affect breast cancer risk?**

There is considerable uncertainty about the relationship between a woman's risk of developing breast cancer and the length of time that she receives HT. Some women take HT for only a few years, until the worst of their menopausal symptoms have passed, while others have taken it for a decade or more. Some researchers believe that there is little or no increased risk of breast cancer associated with short-term use of either HT with estrogen alone or estrogen combined with progestin, while long-term use is linked to an increased risk.

## **What kind of research is underway to answer some of these confusing questions?**

The National Institutes of Health's (NIH) Women's Health Initiative (WHI), the largest clinical trial in the U.S., is exploring the association between HT and the development of breast and colon cancer, heart disease and osteoporosis. On July 9, 2002 the WHI stopped a major clinical trial early due to an increased risk of invasive breast cancer from HT with estrogen and progestin. Results from the rest of this study, available in 2005, should provide us with valuable information on the effect of HT on other diseases of aging. In the meantime, you should discuss these issues with your health care provider. For more information on the WHI study, go to <http://www.nhlbi.nih.gov/health/women/index.htm>.

## **Why is menopausal hormone therapy used in spite of the cancer risk?**

The known benefits of HT can improve the quality of life for many women, by reducing uncomfortable hot flashes, night sweats, and vaginal dryness. There also is evidence that HT helps prevent and treats osteoporosis, and preliminary evidence that it can help prevent other problems associated with age, including Alzheimer's disease, colon cancer and deterioration of eyesight. The addition of progestin to the treatment has dramatically reduced the risk of endometrial cancer. Family history of breast cancer, early age of the first menstrual period (menarche), late age of child bearing, high fat diet, obesity, increased breast density on mammograms, and certain benign breast lesions increase the underlying risk of developing a breast cancer. These factors need to be considered when deciding to take HT. If you are currently taking HT and have concerns, talk with your health care provider as soon as possible.

## **Are there other drug therapies known to treat conditions related to menopause?**

A class of drugs called SSRIs (such as Prozac and Zoloft) is very effective in treating menopause-related symptoms of depression or mood changes. Vitamin E and Clonidine, a drug typically used for high blood pressure, can alleviate hot flashes. To prevent osteoporosis, bisphosphonates, alendronate, raloxifene and calcitonin are used in women who are at high risk for bone loss. Lastly, a class of cholesterol-lowering drugs called HMG-CoA-reductase inhibitors (statins) are proven to be effective for reducing risk of heart disease and are being explored to prevent osteoporosis. No alternatives to estrogen exist for prevention of Alzheimer's disease, colon cancer, and macular degeneration - diseases for which preliminary evidence suggests HT is beneficial.

## **What about herbal remedies?**

There are many "herbal" products for sale that claim to help menopausal symptoms. These products are not regulated through the same government system as drugs, so there is little research to back up their claims. In addition, most have to be taken routinely, are not covered by insurance, and can become costly over time. Any herbal remedies for menopause should be thoroughly discussed with your health care provider. You should tell your provider if you are taking any other medications, since some of the herbal products can have harmful interactions with other drugs.

However, there are some products that seem to help some women. Soy and soy products have been used for the alleviation of menopausal symptoms due to their high concentration of phytoestrogens.

Phytoestrogens are plant-derived compounds that possess estrogenic activity, and therefore could have some of the same effects as HT, but their long-term safety has not been adequately studied. There is limited, and sometimes conflicting, research on the safety and effectiveness of many other popular herbal products that claim to help menopause, including ginseng, black cohosh, dong quai, and evening primrose.

Recently, the American College of Obstetricians (ACOG) issued the following guidelines on the most popular "alternative" medicines for menopause:

1. Soy and Isoflavones (plant estrogens found in beans, particularly soybeans) - High isoflavone intake (about 50 grams of soy protein per day) may be helpful in the short term (2 years or less) in relieving hot flashes and night sweats. Taken over the long term, it also may have beneficial effects on cholesterol and bones. While safe in dietary amounts, the consumption of extraordinary amounts of soy and isoflavone supplements may interact with estrogen and may be harmful to women with a history of estrogen-dependent breast cancer and possibly to other women as well.
2. St. John's wort - May be helpful in the short-term (2 years or less) to treat mild to moderate depression in women (when given in doses of less than 1.2 milligrams a day.) A recent study showed it is not effective in treating severe depression. It also can increase skin sensitivity to the sun and may interfere with prescription antidepressants.
3. Black cohosh - May be helpful in the short term (6 months or less) to treat hot flashes and night sweats. It seems to be extremely safe, although studies have been small and brief, none longer than six months.
4. Chasteberry (also known as monk's pepper, Indian spice, sage tree hemp, and tree wild pepper) - This may inhibit prolactin, a natural hormone that acts on the breast. It is touted for breast pain and premenstrual syndrome. There are very few studies in menopausal women. A study of women with premenstrual syndrome found they reported improvements in mood, anger, headache, breast fullness, but not bloating and other symptoms.
5. Evening primrose - This plant produces seeds rich in gamma-linolenic acid, which some experts believe is the nutritionally perfect fatty acid for humans. Although evening primrose capsules are taken for breast pain, bladder symptoms and menopausal symptoms, there is little or no evidence that they work. The one high quality study of effects on hot flashes found that evening primrose was no better than placebo.



6. Dong quai - A study aimed at reducing hot flashes found that dong quai was not better than placebo - although the 4.5-gram dose used in the study was lower than that typically given in Chinese medicine. The herb is potentially toxic. It contains compounds that can thin the blood, causing excessive bleeding, and make the skin more sensitive to sun, possibly increasing skin cancer risk.
7. Valerian root - This has traditionally been used as a tranquilizer and sleeping aid. But the U.S. Pharmacopoeia, which sets manufacturing standards for medicines, does not support its use, and there have been reports of heart problems and delirium attributed to sudden withdrawal from valerian.
8. Ginseng - Most of the many types of ginseng (including Siberian, Korean, and American, white and red), are promoted for relieving stress and boosting immunity. A study of menopausal women by the leading ginseng manufacturer found the product did not relieve hot flashes but did improve women's sense of well being. Analyses of ginseng products have found a troubling lack of quality control: some contained little or no ginseng, contained large amounts of caffeine, or were tainted by pesticides or lead.
9. Wild and Mexican yam - There are no published reports that show wild and Mexican yam cream is effective in helping menopausal symptoms. The hormones in wild and Mexican yam do not have any estrogenic or progestational properties, so they are not expected to help women with these symptoms.

## **Who should not use HT?**

HT is often not recommended for women who have any of the following conditions:

- Vaginal bleeding of an unknown cause
- Suspected breast cancer or history of breast cancer
- History of endometrial cancer or cancer of the uterus
- Chronic disease of the liver
- History of heart disease
- History of venous thrombosis (blood clots in the veins or legs, or in the lung). This includes women who have had thrombosis or blood clots during pregnancy or when taking birth control pills. Although the risk of blood clots in women is very low, HT increases the risk.

## **How can I sort through the benefits and risks to make a good decision about whether or not to use postmenopausal hormone therapy?**

Here are several points to help you summarize the findings of the Women's Health Initiative (WHI) study:

First, it's important to know that, because the study involved healthy women, only a small number of them had either a negative or positive effect from estrogen plus progestin therapy. The percentages describe what would happen to a whole population-not to an individual woman. For example, the increased risk of breast cancer for the women in the WHI study who were taking the estrogen plus progestin therapy was less than a tenth of 1 percent each year. But if you apply that increased risk to a large group of women and over several years, then the number of women affected becomes an important public health concern. About 6 million American women take estrogen plus progestin therapy. That would translate into nearly 6,000 more cases of breast cancer every year- and, if all of the women took the therapy for 5 years, that might result in 30,000 more cases of breast cancer.

Second, bear in mind that percentages aren't fate. Whether expressing risks or benefits, they do not mean you will develop a disease. Many factors affect that likelihood, including your lifestyle and other environmental factors, heredity, and your personal medical history. Finally, realize that most treatments carry risks and benefits. No one can make a treatment choice for you. Talk with your doctor or other health care provider and decide what's best for your health and quality of life. Begin by finding out your personal risk profile for heart disease, stroke, breast cancer, osteoporosis, colorectal cancer, and other conditions. Discuss quality of life issues and alternatives to postmenopausal hormone therapy with your health care provider. Then, weigh every factor carefully and choose the best option for your health and quality of life. And keep talking with your health care provider-your health status can change and so can your choice.

## **For more information...**

You can find out more about hormone therapy by contacting the National Women's Health Information Center 800-994-WOMAN (9662) or the following organizations:

### **National Heart, Lung, and Blood Institute Information Center**

Phone: (301) 592-8573

Internet Address: <http://www.nhlbi.nih.gov/health/women/index.htm>

### **National Institute on Aging**

Phone: (800) 222-2225

Internet Address: <http://www.nih.gov/nia/>

### **National Center for Complementary and Alternative Medicine**

Phone: (888) 644-6226, TTY: (888) 644-6226

Internet Address: <http://nccam.nih.gov/>

### **North American Menopause Society**

Phone: (440) 442-7550

Internet Address: <http://www.menopause.org/>

### **American College of Obstetricians and Gynecologists**

Phone: (202) 863-2518

Internet Address: <http://www.acog.org/>

### **The Hormone Foundation**

Phone: (800) 467-6663

Internet Address: <http://www.hormone.org/>

## **Women's Health Initiative (1-800-54-WOMEN)**

Phone: (301) 402-2900

Internet Address: <http://www.nhlbi.nih.gov/whi/index.html>

This information was adapted from NHLBI's "Facts about Postmenopausal Hormone Therapy"

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